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PATENT

Atty. Docket No.
AR02366USACON3

Date: August 20, 2003 By: 
Lois E. Miller

CN 2777

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: George GUILTARD et al.

Art Unit: to be assigned

Serial No.: herewith

Examiner: not yet assigned

Filed: herewith

For: METHOD FOR MANAGEMENT OF
INCONTINENCE

Mail Stop: Patent Application
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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with the first or second After Final Submission, therefore:

- Statement in Accordance with §1.97(e) (attached); or
- Please charge Deposit Account No. 10-0750 the fee of \$180.00 as set forth in §1.17(p).

In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- Statement in Accordance with §1.97(e) (attached); or
- Please charge Deposit Account No. 10-0750 the fee of \$180.00 as set forth in §1.17(p).

In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

Copies of references **BK-BZ** and **CB-CF** listed on the attached Form PTO-1449 are enclosed herewith.

Copies of the following references listed on the attached Form PTO-1449 are **NOT** enclosed herewith:

In view of the voluminous nature of references _____, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

Copies of references **AA-BJ** and **CA** are not provided because they were previously cited or submitted to the Office in prior applications:

USSN: 09/785,805, filed 02/16/01, (pending);

USSN: 09/280,309, filed 03/29/99, (Now Patent 6,262,115);

USSN: 08/806,773, filed 02/26/97 (Now Patent 5,912,268);

USSN: 08/706,576, filed 09/05/96 (Now Patent 5,840,754);

USSN: 08/445,849, filed 05/22/95 (Now Patent 5,674,895).

If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

There are no listed references which are not in the English language.

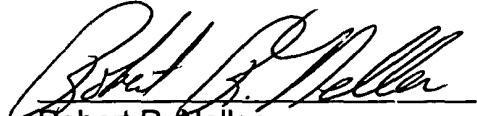
The relevance of those listed references which are not in the English language is as follows:

Attached are copies of PCT Search Reports from corresponding PCT applications PCT/US96/06639 and PCT/IB98/01982.

Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

Respectfully submitted,



Dated: August 19, 2003
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Enclosures:

1. PTO FORM 1449 (3 sheets)
2. PCT Search Report dated August 13, 1996 (3 pages);
3. PCT Search Report dated April 28, 1999 (3 pages);
4. References **BK – BZ** and **CB – CF** (21 references).

| FORM PTO-1449 | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO.: AR02366USA CON3 | SERIAL NO.: TO BE ASSIGNED | | |
|--|-----------------|--|-----------------|--|--------------------------------------|-----------|----------------------------|
| INFORMATION DISCLOSURE STATEMENT FOR PATENT <i>(Use several sheets if necessary)</i> | | | | APPLICANT: George GUITTARD, et al. | | | |
| | | | | FILING DATE: Herewith | GROUP: to be assigned | | |
| U. S. PATENT DOCUMENTS | | | | | | | |
| *EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | | CLASS | SUB-CLASS | FILING DATE IF APPROPRIATE |
| AA | 6,262,115 | 07/17/01 | GUITTARD et al. | | | | |
| AB | 6,124,355 | 09/26/00 | GUITTARD et al. | | | | |
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| BC | 3,992,518 | 11/16/76 | CHEIN et al. | | | | |
| EXAMINER | | | DATE CONSIDERED | | | | |
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | | | | |

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| | | | | FILING DATE: Herewith | GROUP: to be assigned | | |
| U. S. PATENT DOCUMENTS | | | | | | | |
| BD | 3,962,414 | 06/08/76 | MICHAELS | | | | |
| BE | 3,916,899 | 11/04/75 | THEEUWES et al. | | | | |
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| | BK | WO 96/37202 | 11/28/96 | PCT | | | X |
| | BL | WO 96/12477 | 05/02/96 | PCT | | | X |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | |
| | BM | Michael M. Coleman, et al., <u>Polymer</u> , 31:1187-1231, July 1990. "A Practical Guide to Polymer Miscibility" | | | | | |
| | BN | KODAMA KK, <u>DATABASE WPI, AN</u> : 94-068306, Derwent Publications Ltd., Jan. 18, 1994. "Sustained release preparation of oxybutynin chloride - comprises oxybutynin chloride, acidic substance, gelling agent and higher alcohol" | | | | | |
| | BO | KODAMA KK, <u>DATABASE WPI, AN</u> : 94-031722, Derwent Publications Ltd., Dec. 21, 1993. "Pharmaceutical preparations for prolonged action against urinary incontinence - comprise sustained release oxybutynin chloride for pharmaceutical compsn. sustained release coating film of non water soluble polymers and/or ethylcellulose" | | | | | |
| | BP | Enomoto, et al., <u>Chemical Abstracts</u> , 120(18):227011, May 2, 1994. "Sustained release preparation of oxybutynin chloride" | | | | | |
| | BQ | Enomoto, et al., <u>Chemical Abstracts</u> , 120(14):173499, April 4, 1994. "Sustained release formulations containing oxybutynin chloride" | | | | | |
| | BR | Julian H. Fincher, <u>J. Pharm Sci.</u> , 57(11):1825-1835, November 1968. "Particle Size of Drugs and Its Relationship to Absorption and Activity" | | | | | |
| | BS | P. Grafton, <u>Modern Plastics Encyclopedia</u> , 46:62-70, 1969. "General principles for designing with plastics" | | | | | |
| | BT | Suneel K. Gupta, et al., <u>Clinical Pharmacology & Therapeutics</u> , 61(2):Abstract PIV-26, 1997. "Evidence of Site Specific Presystemic Metabolism of Oxybutynin Following Oral Administration" | | | | | |
| | BU | K.W. Leong & R. Langer, et al., <u>Advanced Drug Delivery Reviews</u> , 1:199-233, 1987. "Polymeric controlled drug delivery" | | | | | |
| | BV | Robert J. Linhardt, <u>Controlled Release of Drugs: Polymers and Aggregate Systems</u> , Ch.2, pp.53-95, 1989. "Biodegradable Polymers for Controlled Release of Drugs" | | | | | |
| EXAMINER | | | | DATE CONSIDERED | | | |
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| | | FILING DATE: Herewith | GROUP: to be assigned | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | |
| BW | S.M. Lu & Jun-Ying Yu, <u>Inter. J. Pharm.</u> , 112:117-124, 1994. "Dimensionless Presentation for Drug Release from a Coated Pure Drug Bead: 2 Experiment," | | | |
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| CA | <u>Roerdink, et al.</u> , <u>Drug Carrier Systems</u> , 9:57-109, 1989. | | | |
| CB | W.J. Roff et al., <u>Handbook of Common Polymers</u> , CRC Press, Cleveland Ohio, 1971. | | | |
| CC | <u>The United States Pharmacopia - The National Formulary</u> , USP23:NF18, pp. 1791-1796, 1995. "<711> Dissolution" | | | |
| CD | <u>The United States Pharmacopia - The National Formulary</u> , USP XXII / NF XVII, pp. 1578-1579, 1990. "<711> Dissolution" | | | |
| CE | Dale E. Wurster, <u>J. Am. Pharm. Assoc</u> , 48(8):451-454, August 1959. "Air-Suspension Technique of Coating Drug Particles" | | | |
| CF | Dale E. Wurster, <u>J. Am. Pharm. Assoc</u> , 49(2):82-84, February 1960. "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II" | | | |
| EXAMINER | | DATE CONSIDERED | | |
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